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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,366	01/10/2002	Iwao Katsuyama	KUP-D0135	6348

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

15

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,366	KATSUYAMA, IWAO	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41, 42, 44-47, 49-56, 58, 59, 61-69 and 71-75 is/are pending in the application.
- 4a) Of the above claim(s) 41 and 42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49-54, 62, 65, 68 and 71-75 is/are allowed.
- 6) ☒ Claim(s) 44-47, 55, 56, 58, 59, 61, 63, 64, 66, 67, 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office Action is a response to the "Amendment under 37 CFR § 1.111" filed 19 June 2003 (Paper No. 14) in reply to the Non-Final Office Action mailed 20 March 2003 (Paper No. 13). Claims 44-72 were considered in Paper No. 13. Claims 48, 57, 60 and 70 were canceled, claims 44, 55, 58, 71 and 72 were amended and claims 73-75 were added in Paper No. 14. Claims 41, 42, 44-47, 49-56, 58, 59, 61-69 and 71-75 are pending. Claims 41 and 42 are withdrawn from consideration and claims 44-47, 49-56, 58, 59, 61-69 and 71-75 are under consideration.

Election/Restrictions

This application contains claims 41 and 42 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

Rejection of claims 48, 57, 60 and 70 is rendered moot by cancellation of the claims.

Claim Rejections - 35 USC § 112

Rejection of claims 71 and 72 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in view of the amendments.

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Claim Rejections - 35 USC § 102

Claims 44-47, 55, 56, 58, 59, 61 and 63 stand rejected under 35 U.S.C. 102(b) as anticipated by Gilbard *et al.* (1984) *Ophthalmology* 91:1205-1212 for reasons of record and herein below in the response to arguments.

Claim Rejections - 35 USC § 103

Claims 64, 66, 67 and 69 stand rejected under 35 U.S.C. 103(a) as unpatentable over Yerxa *et al.* (1999; U.S. Patent No. 5,900,407) in view of Gilbard (1984; *supra*) and in further view of Fujihara *J. Ocular Pharm.* (1995) 11:503-508 for reasons of record and herein below in the response to arguments.

Response to Arguments

Claim Rejections - 35 USC § 102

In response to rejection of claims 44-47, 55, 56, 58, 59, 61 and 63 as anticipated by Gilbard *et al.*, Applicant has amended claim 44 such that it is now limited to contacting the “whole area of the ocular cornea or a part thereof” (claim 44; emphasis added) with a water absorbing material in the physical state of powder, gel, jelly or tablet. Applicant has further limited claim 55 to contacting a part or a pupil area of the ocular cornea with said water-absorbing material.

Applicant argues that, because the claims are limited to contacting a part or a pupil area of the ocular cornea with the water absorbing material, the corneal epithelial damage is formed in a part of the cornea. This argument has been fully considered but is not found persuasive. First,

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as claim 44 is not limited to contacting only a part of the cornea with the water-absorbing material, clearly the damage is not limited to only a part of the cornea. Next, although the water absorbing material might be applied to a limited area, the water absorbing material would be expected to diffuse away from the site of application and induce damage over the entire corneal surface, particularly in the case of application as powder. Thus the claimed animal is not limited to an animal having corneal epithelial damage in a part or pupil area of the ocular cornea and the claims still encompass the animal taught by Gilbard *et al.* If the claims were instead limited to an animal comprising corneal epithelial damage in a part of the ocular cornea or in the pupil area of the ocular cornea, the claims would be free of the art.

Claim Rejections - 35 USC § 103

In response to the rejection of claims 64, 66, 67 and 69 as unpatentable over Yerxa *et al.* in view of Gilbard *et al.* and in further view of Fujihara, Applicant argues that, because the claims are directed to a method of using the animal of claim 44, and claim 44 is not anticipated by the teachings of Gilbard *et al.*, the claims are not obvious over the teachings of the prior art. This argument has been fully considered but is not found persuasive because, for the reasons set forth above, the teachings of Gilbard *et al.* still anticipate the experimental animal of claim 44.

Applicant further argues, "Applicants have found for the first time that the corneal epithelial damage can be caused by the use of a water-absorbing material in the physical state of powder, gel jelly or tablet. Since the references cited by the Examiner neither teach nor suggest this new finding, the model animal of the present invention cannot be obtained even when referred to these cited references" (page 16). This argument is not found persuasive because

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Gilbard *et al.* teaches a method of making an animal having corneal epithelial damage by exposing the cornea to an osmotic agent, which would be expected to produce the same damage regardless of whether that agent was in the form of a solution, or in some solid or semisolid state at the time of application. Although Applicant argues that the animal can be prepared in 60 minutes as opposed to the 4.5 hours for the animal of Gilbard *et al.*, there is no evidence that the animal produced by the instant method after 60 minutes is different from the animal produced by the method of Gilbard after 4.5 hours. Because the claimed method recites only that the animal produced according to the method of claim 44 is used therein, any method of using an equivalent animal reads on the claim regardless of how long it took to produce the animal.

Finally, Applicant argues that in the instant method the evaluation can be made accurately by using an areal of a damaged site as an objective index. This contention presumably relates back to Applicant's assertion that the animal of claim 44 is limited to comprising damage limited to a defined area less than the size of the entire cornea. However, as pointed out above, the animal of claim 44 encompasses an animal produced by contacting the whole area of the ocular cornea with a water-absorbing material. Therefore, the animal used in the method is the same as the animal taught by Gilbard *et al.* and the method as a whole stands rejected as obvious over the teachings of the prior art.

Allowable Subject Matter

Claims 49-54, 62, 68 and 71-75 are allowed.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

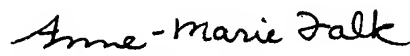
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
August 10, 2003


ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER